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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/001,737	12/31/97	MIZZEN L	870109.408

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EXAMINER	
FIELDS, I	
ART UNIT	PAPER NUMBER
1645	11

DATE MAILED: 04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application N .	Applicant(s)	
	09/001,737	MIZZEN ET AL.	
	Examiner	Art Unit	
	Iesha P Fields	1645	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1,9-18, and 25-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8, and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of Group II is acknowledged. Applicant's were further restricted to a single sequence for examination and elected SEQ ID No. 7. A topographical error was made in the grouping of claims 9-10 which belongs in Group I. Consequently, Claims 2-8, 19-24, 31(Group II) and SEQ ID No.7 are under examination in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 2-8 and 31 rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for an isolated nucleic acid molecule encoding a *Streptococcus pyogens* Hsp60 protein it does not reasonably provide enablement for an isolated nucleic acid molecule encoding a polypeptide having at least one amino acid difference from a corresponding polypeptide of an Hsp60 protein from an organism other than Streptococcus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to a composition comprising an isolated nucleic acid molecule wherein the isolated nucleic acid molecule encodes a polypeptide having at least one amino acid difference from a corresponding polypeptide of an Hsp60 protein from an organism other than *Streptococcus*.

The claims encompass any organism other than *Streptococcus*. However, the specification only teaches of nucleic acid molecules encoding Hsp60 proteins derived from *Streptococcus pneumoniae and Streptococcus pyogens.* In view of the lack of guidance, the lack of examples, and the lack of predictability associated with regard to producing and using the myriad or derivatives encompassed in the scope of the claims one skilled in the art would be forced into undue experimentation in order to practice the broadly claimed invention.

2. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 5 recites a nucleotide sequences that is identical to a segment comprising at least 25% of the contiguous nucleotide bases set forth in SEQ ID NO: 7.

The specification and claim does not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 7 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

2. Claims 3, 7, 19-24 and 31 are vague and indefinite in recitation of under 35 U.S.C. 112, second paragraph, in recitation of "conditions of high stringency".

The claims are directed to an isolated nucleotide sequence set forth in SEQ ID NO:7 or a complement thereof under conditions of high "stringency". Possibilities for hybridization are determined by the stringency of the procedure. Stringency, determined by the physical and chemical conditions, establishes the degree of hybridization. Applicant has not provided a clear definition of the temperature at which the hybridization takes place or a clear definition of the chemical conditions under which the stringency is to take place. Without a clear definition as to the physical and chemical conditions as to which the hybridization are to occur, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in recitation of "specifically hybridizes". One of skill in the art would be unable to determine the meets and bounds of such a limitation. For instance, what level of hybridization does the applicant intend? Without a clear definition as to what level of hybridization is intended by the applicant, one of skill in the art would be unable to replicate the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Birkett et al.

The claims are drawn to a nucleotide sequence which hybridizes under conditions of high "stringency" to a nucleotide sequence set forth in SEQ ID NO: 7, or a complement thereof.

Birkett et al (U.S. Patent Number 5,302,527) disclose of random priming with a mixed hexamer oligonucleotide kit (Multiprime Kit, Amersham). (See column 15 lines 25-30).

In view that the random hexamer oligonucleotides will hybridize to the nucleotides of the instant invention under stringent conditions, and that the claims do not recite a length of the isolated polynucleotide, the disclosure of the hexamer kit by Birkett et al is seen to anticipate the claimed invention.

Claim Rej ctions - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2-5, 7, 9-10, 19-24 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Srivasta et al. in view of Hamel and Suzue et al.

The claims are drawn to a vector comprising an isolated nucleic acid molecule encoding a Streptococcus Hsp60 protein.

Srivasta et al. (WO 95/254923) disclose methodologies for isolating Hsp60 polypeptides in several pathogenic organisms including bacteria. Srivasta et al. further disclose methods of making and using recombinant heat shock proteins.

Srivasta et al. does not teach of an isolated nucleic acid molecule encoding a *Streptococcus pyogenes* Hsp60 protein.

Hamel et al (WO 96/40928) teach of isolated nucleotide sequences encoding *Streptococcus* heat shock proteins derived from *Streptococcus pygenes* and *Streptococcus* pneumoniae species.

Suzue et al (in Freige et al. (eds) 1996 pp. 449-463) teach that heat shock proteins when used as a subunit vaccine, stimulate protective immunity in animal models.

Given that 1) Srivasta et al. has taught of isolating Hsp60 polypeptides in pathogenic organisms and expressing the polypeptides in a suitable vector and that 2) Hamel et al. has taught of isolating the nucleotide sequences encoding Streptococcus heat shock proteins and that 3) Suzue et al. has taught that heat shock proteins when used as a subunit vaccine, stimulate protective immunity in animal models it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to isolate nucleic acid molecules encoding heat shock proteins (i.e. Hsp60, Hsp70, Hsp90) in *Streptococcus*. One would have been motivated to isolate such a nucleic acid molecule because heat shock proteins are among the most conserved proteins in existence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

April 6, 2001

MARK NAVARRO
PRIMARY EXAMINER